

# **Small Business Regulatory Fairness Board**

## **Small Business Impact Statement**

**Date:** July 25, 2016

**Rule Number:** 20 CSR 2220-2.200 – Sterile Pharmaceuticals

**Name of Agency Preparing Statement:** DIFP, Professional Registration, State Board of Pharmacy

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**Name of Person Approving Statement:** Sarah Ledgerwood

### **Please describe the methods your agency considered or used to reduce the impact on small businesses**

The proposed emergency/amended rule was posted on the Board's website for public comment and small businesses were specifically asked for comments and suggestions. Additionally, the proposed amendment was discussed during open session meetings of the Board in January, April and May of 2016. The proposed amendment was also provided to representatives from the Missouri Pharmacy Association which represents a significant number of small and independent pharmacy owners.

### **Please explain how your agency has involved small businesses in the development of the proposed rule.**

The proposed emergency/amended rule was provided to representatives from the Missouri Pharmacy Association in May 2016. The Missouri Pharmacy Association represents and includes a significant number of small and independent pharmacy owners. Additionally, the Board currently includes a small business owner who performs sterile compounding who was extensively involved in drafting and reviewing the proposed rule. The proposed rule was also reviewed by the Board's Chief Inspector who is also a small pharmacy business owner and also participated in drafting.

A more extensive version of the proposed emergency/amended rule was made available to the public in the fall of 2015 and also included in the Board's newsletter. The current proposed amendment was significantly revised and shortened in response to comments from small business owners regarding feasibility and potential fiscal impact.

**Please list the probable monetary costs and benefits to your agency and any other agencies affected. Please include the estimated total amount your agency expects to collect from additionally imposed fees and how the moneys will be used.**

The Board does not anticipate any additional public costs or fiscal benefits. The proposed amendment does not require any additional fees.

**Please describe small businesses that will be required to comply with the proposed rule and how they may be adversely affected.**

Small sterile compounding pharmacies will be required to comply with the amended requirements. It should be noted the proposed amendment was significantly revised and shortened in response to comments from small business owners regarding feasibility and potential fiscal impact.

**Please list direct and indirect costs (in dollars amounts) associated with compliance.**

As reflected in the attached private fiscal note, the Board estimates private fiscal impact of \$2,960,504.35 annually over the life of the rule. The Board further estimates an additional \$99,245 in private fiscal costs during the first year of rule implementation.

It should be noted that the Board conducted a survey in 2014 which indicated over 75% of pharmacies are currently complying with the majority, if not all, of the proposed rule requirements. Accordingly, the Board estimates private fiscal impact will likely be significantly lower than estimated, however, costs have been estimated as reflected in the private fiscal note to ensure full compliance with Chapter 536, RSMo.

**Please list types of business that will be directly affected by, bear the cost of, or directly benefit from the proposed rule.**

Sterile compounding pharmacies.

**Does the proposed rule include provisions that are more stringent than those mandated by comparable or related federal, state, or county standards?**

Yes \_\_\_\_ No X

**If yes, please explain the reason for imposing a more stringent standard.**

*For further guidance in the completion of this statement, please see §536.300, RSMo.*